

REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of three months of the period for response to the Office Action.

Authorization to charge the prescribed fee to our deposit account is enclosed.

The Examiner indicated that claims 1 to 11 were withdrawn from consideration as being directed to a non-elected invention. Claims 1 to 11 have been deleted, such deletion being made without prejudice to applicants right to file a divisional or continuation application directed to the subject matter thereof.

The Examiner commented on the IDS filed herein. The listing of references on pages 13 to 15 was not intended to replace a list pursuant to 37 CFR 1.98(b). Indeed an IDS was filed and is acknowledged in the attachment to the Office Action. The Examiner is thanked for pointing out and correcting clerical errors with respect to #29 and #32 on the IDS.

The Examiner objected to the abstract as not being submitted on a separate sheet of paper. This matter is corrected herewith.

The Examiner indicated that the specification did not comply with 37 CFR 1.821 to 1.825 with respect to a Sequence Listing. Enclosed herewith are a Sequence Listing in computer readable form and paper form. By this amendment, the paper copy is directed to be inserted in the specification. It is stated, under the signature of the undersigned, that the computer-readable form and paper copy of the Sequence Listing are the same.

The Examiner rejected claims 12 to 23 under 35 USC 112, first paragraph, on the basis that the specification, while being enabled for a method of inducing an immune response, does not reasonably provide enablement for a protective immune response induced by a vaccine. The Examiner indicated that the specification did not enable any person skilled in the art to which it pertain, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is submitted that the claims are fully enabled. The Examiner indicates that claims 12 to 23 can be considered in two ways. In the first way, the claims can be read to encompass a method wherein an immune response is activated in a host, which is interpreted simply as the host generating antibodies against a foreign antigen. The Examiner considers the claims in this interpretation to be enabled.

The Examiner, however, considers there to be a second interpretation in which the method of generating an immune response also confers protection of a host against the disease caused by infection with a strain of *Chlamydia*. The Examiner considers that the second situation gives raises to the issues of enablement.

However, it is submitted that the claims are capable only of the initial interpretation since claim 12 lacks any recitation of protection. Claim 12 states:

“A method of using a gene encoding a serine-threonine kinase (STK) of a strain of *Chlamydia* or a fragment of said STK which generates a STK specific immune response, to produce an immune response in a host”
(emphasis added)

The claim promises no more than “an immune response”, which is indicated by the Examiner to be enabled. Nowhere does the claim refer to a protective immune response.

Accordingly, it is submitted that claims 12 to 23 are fully enabled and hence the rejection of claims 12 to 23 under 35 USC 112, first paragraph, as lacking an enabling disclosure, should be withdrawn.

The Examiner rejected claims 12 to 21 under 35 USC 103(a) as being unpatentable over Alberts et al in view of Su et al, Stephens et al and Pardoll and Beckerieg.

As the Examiner notes claims 12 to 21 are directed to a method of using a gene encoding serine-threonine kinase (STK) of a strain of *Chlamydia* or a fragment of the said STK that generates a STK-specific immune response.

The Examiner asserts that, at the time of filing of the application, the art has shown that skilled artisans were actively trying to induce immunity to *Chlamydia* in host animals. The Examiner cites as an Example, the Su et al article which describes the generation of antibodies against *Chlamydia* MOMP following subcutaneous immunization with MOMP peptide. This article is acknowledged in the specification (ref. 32). The Examiner indicates that the reference demonstrates that one indicator that the skilled person used to determine whether an immune response was invoked was to check the sera of the host animal for antibodies against the target protein. The applicants agree.

The Examiner indicates that Alberts et al is relied on for a teaching that "almost any macromolecule, as long as it is foreign to the recipient, can induce an immune response". The applicants agree. As the Examiner comments, Alberts et al do not teach the amino acid sequence of *Chlamydia* STK and neither do Su et al.

However, it is important to note that applicants claims are directed to a method of using a gene encoding STK and not STK itself. The applicants isolate the gene, operatively link the gene to a control sequence to produce a non-replicating vector in which the control sequence directs expression of the STK when introduced into a host. Thus, the present invention is concerned with the use of a DNA vector which is introduced to a host.

The Examiner comments that the Stephens et al teach the genome sequence of *Chlamydia trachomatis* as well as the amino acid sequence of *Chlamydia* STK. The Examiner comments that:

"While Stephens et al do not demonstrate a one-to-one relationship between the amino acid sequence and the corresponding nucleotide sequence, an artisan of ordinary skill in that art can reverse translate the protein sequence to a nucleotide sequence and obtain a nucleotide sequence same as that of SEQ ID NO: 1."

(emphasis added)

It is submitted that such is not the case. While the genetic code permits nucleotide sequences to be translated into amino acid sequences, the degeneracy of the genetic code does not permit with certainty the reverse translation of an amino acid sequence to a nucleotide sequence which actually encodes the amino acid sequence. Whatever Stephens et al may teach with respect to the amino acid sequence of *Chlamydia* STK, that does not teach the nucleotide acid sequence encoding that amino acid sequence.

It is agreed with the Examiner that Pardoll and Beckerieg teach that injection of naked DNA may produce immune responses. These references are, of course, limited in their teaching to the specific material tested, although it is agreed that the prior art contains a number of examples where DNA immunization has produced an immune response in a host. As noted on page 2, the inventor has previously obtained a protective immune response using a DNA sequence encoding MOMP of *C. trachomatis* in a plasmid by DNA immunization (see USP 6,235,290). However, this is not predictive that an immune response to a gene encoding STK could be obtained by DNA immunization.

Having regard to the above discussion of the combined teachings of the prior art, it is submitted that the combination of prior art fails to disclose or suggest applicants method as defined in claims 12 to 21. There simply is no

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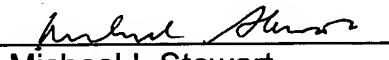
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suggestion in the prior art that an immune response to a gene encoding *Chlamydia* STK could be obtained.

It is submitted, therefore, that claims 12 to 21 are patentable over the applied prior art and that the rejection of claims 12 to 21 under 35 USC 103(a) as being unpatentable over Alberts et al, in view of Su et al, Stephens et al and Pardoll and Beckerieg, should be withdrawn.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,


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